APR 1 8 2001

K010172

arplay medical

Premarket Notification [510(k)] Summary
Tab 4

January 5, 2001

radiothérapie
radiotherapy
•
curiethérapie
brachytherapy
•
radioprotection

Trade Name: Lead Blocks

Common Name: Beam Blocks for Radiation Therapy

Classification Name: Radiation Therapy Beam Shaping Block, 90 IXI (per 21 CFR section 892.5710)

Manufacturer's Name: Arplay Medical S.A.
Address: 1 Route de Citeaux
21110 Izeure
France

Corresponding Official: Richard Borgi, MD
Title: President and CEO
Telephone: +33-3-8029 7401
Fax: +33-3-8029 7622

Predicate: Aktina Medical Physics Corp., Photon Beam Blocking System, K974239

Device Description: The Arplay Medical Lead Blocks are intended to shape the beam from a radiation therapy source. They are available in heights to attenuate the radiation from both linear accelerators and cobalt treatment machines.

The Lead Blocks are fabricated from lead, with screw mounts or rubber compression mounts to meet the customer's requirements. The screw mount blocks are designed to be attached to beam block trays with appropriate holes or slots. Those with rubber compression mounts are designed to be compressed between two appropriately designed beam block trays.

The Lead Blocks are formed in a variety of shapes including squares, rectangles, triangles, ovoids and a combination thereof as required by the customer.

Intended Use: To shape the beam from a radiation therapy source.

Technological Characteristics: See the attached predicate comparison table.

#	Feature	Photon Beam Blocking System, K974239	Arplay Medical Lead Blocks
1	Material	Lead	Lead
2	Linac Model	Yes	Yes
3	Cobalt Model	Yes	Yes
4	Mounting	Screw mount	Screw or rubber compression mount
5	Multiple Shapes	Yes	Yes

The Arplay Medical Lead Blocks have the same intended use and performance characteristics as the predicate device. No new issues of safety of effectiveness are introduced by this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2001

Richard Borgi, M.D.
President and CEO
Arplay Medical S.A.
1Route de Citeaux
21110 Izeure
FRANCE

Re: K010172
Lead Blocks
Dated: January 5, 2001
Received: January 18, 2001
Regulatory Class: II
21 CFR §892.5710/Procode: 90 IXI

Dear Dr. Borgi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Tab 3

Indications For Use

510(k) Number: K010172

Device Name: Lead Blocks

Indications for Use:
To shape the beam from a radiation therapy source.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use___
(per 21 CFR 801.109)

David G. Jayne

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010172